IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, Plaintiffs, vs. XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES, Defendants.	CIVIL ACTION NO. 1:23-cv-00707

COMPLAINT

Plaintiffs the National Infusion Center Association (NICA), the Global Colon Cancer Association (GCCA), and the Pharmaceutical Research and Manufacturers of America (PhRMA) allege as follows:

INTRODUCTION

1. America leads the world in pharmaceutical and biotechnology research, making the United States the dominant force for life-changing innovation. The American biopharmaceutical

and medical industries, including members of plaintiffs NICA and PhRMA, have saved and enhanced lives both at home and abroad by developing and administering cutting-edge, first-in-class medicines to prevent and treat a wide range of serious maladies, including cancers, cardiovascular conditions, autoimmune disorders, and infectious diseases. Conditions that were once fatal are now treatable thanks to advancements in pharmaceutical research. And conditions that were once treatable only with risky and expensive procedures, like surgery followed by lengthy hospital stays, are now treatable medically on an outpatient basis or at home, providing immeasurable health and economic benefits to patients.

2. Companies have achieved these breakthroughs only by making enormous investments—and running enormous risks. It takes billions of dollars and years of effort to develop a single drug or therapeutic treatment. And anyone willing to invest those resources must take on extraordinarily unfavorable odds: Among the small share of investigational medicines that get as far as entering clinical trials, only 12% ever achieve approval by the U.S. Food and Drug Administration (FDA), and of those approved, only one in five will generate revenues that exceed the average cost of developing a medicine. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25–26 (2016), https://bit.ly/30UAIdg; John A. Vernon et al, *Drug Development Costs When Financial Risk is Measured Using the FAMA-French Three-Factor Model,* Health Econ 2010:19(8), https://onlinelibrary.wiley.com/doi/10.1002/hec.1538. The risk-reward calculus, moreover, is becoming even more precarious; development costs are rising steeply, while potential returns on investment are becoming slimmer and more uncertain as drug treatments become increasingly personalized. *See Research and Development in the Pharmaceutical Industry*, Congressional Budget Office 16–17 (Apr. 2021), https://www.cbo.gov/publication/57126; U.S. Dep't of Health

& Human Servs. & U.S. Food & Drug Admin., *Paving the Way for Personalized Medicine* 4 (Oct. 2013), https://bit.ly/3Vfj0un.

3. Medicare has traditionally encouraged pharmaceutical innovation through market-based mechanisms. Since its inception, the program has reimbursed covered drugs in a manner that promotes patient access, while permitting pharmaceutical manufacturers the opportunity to earn competitive returns that encourage and fund future innovation. In particular, Congress sought to ensure that Medicare reimburses the costs of these drugs at rates based on prices negotiated in real market transactions.

4. This market-based system for encouraging innovation benefits manufacturers, providers, and patients. Manufacturers of successful products, including members of PhRMA, can earn returns sufficient to fund further research and development. Providers of those products, including members of NICA, can receive reimbursements sufficient to support their operations—including operating outpatient facilities for administering biological treatments via infusion or injection. And patients, including those represented by GCCA, can receive innovative, cutting-edge treatments for serious medical conditions—even if they live in rural areas without extensive hospital capacity.

5. Congress's recently enacted Inflation Reduction Act of 2022, Pub. L. 117-169 (IRA or the Act), however, upends this time-tested, market-based system for encouraging innovation. In its place, Congress established a system of price controls, seeking to reduce expenditures even at the cost of drastically slowing innovation, reducing drug availability, and worsening patient outcomes. But that type of scheme, if implemented transparently, would come at a high cost for Congress, resulting in significant public criticism and political blowback. Had Congress made

clear that it was mandating price controls, the resulting drug shortages, rationing, and declining innovation would be clearly attributable to the elected officials who supported the law.

6. With so much at stake—both practically and politically—the natural and prudent course would have been for Congress to carefully choose the mechanism for setting drug prices. And if Congress had simply established the price-setting mechanism itself, the need for procedural protections would have been plain: Similar price- and rate-setting mechanisms that Congress has established in the past all include safeguards against arbitrary or unreasonable governmental decision-making—such as clear standards to guide and constrain agency pricing decisions, to ensure fair compensation, and to protect consumers against market distortions, as well as meaningful judicial review to protect investment-backed expectations.

7. But Congress opted for a very different course in the IRA. It adopted a novel, Byzantine structure that, at every turn, attempts to obscure the process by which prices are imposed. The resulting scheme eliminates transparency, avoids accountability, and attempts to foreclose judicial review. It is a sham.

8. As an initial matter, Congress did not undertake the politically fraught task of setting drug prices itself, instead delegating nearly unfettered discretion to the Secretary of the Department of Health and Human Services (HHS). But rather than have HHS set prices transparently, the IRA attempts to disguise price controls set by government *fiat* through a deceptively named "Drug Price Negotiation Program" (Drug Pricing Program or Program). In fact, the Program involves no genuine "negotiation" at all. Instead, it *compels* pharmaceutical manufacturers to accept prices that are capped at whatever price HHS chooses, while setting no meaningful constraints on HHS's new price-setting powers.

9. What is more, the Drug Pricing Program then forces manufacturers to deliver a government-approved message, compelling them to "agree" to the government-dictated price—what the law calls "the maximum fair price"—under threat of a crippling excise tax for non-acquiescence. The "tax" itself is staggering, reaching as high as *1,900%* of a manufacturer's *total U.S. revenues* for a drug. Worse still, the law provides for no price floor; HHS could take the position that a selected drug is worth $1 per dose, and the manufacturer must either sell at that price or take on massive liability. The only alternative provided is to exit the Medicare and Medicaid programs altogether, withdrawing not just the drug in question, but *all* of the manufacturer's drugs. But even that (practically infeasible) choice is constrained by a statutorily mandated delay of 11 to 23 months—during which time the manufacturer is forced to continue participating in the sham "negotiation." And providers are caught up in this morass as well, since their reimbursement rates are based on the price HHS imposes on the manufacturer.

10. Finally, Congress insulated the program from accountability at every stage, from implementation to enforcement. At least as HHS reads the statute, HHS need not engage in notice-and-comment rulemaking or even solicit public comment regarding key aspects of the Program's implementation. Strikingly, the IRA's text purports to foreclose *all* administrative and judicial review of critical implementation decisions. And HHS, through the Centers for Medicare & Medicaid Services (CMS), now has proposed to prevent manufacturers from disclosing *any* information about the process by which the agency imposes its price controls.

11. At bottom, HHS could decree any price it wants for a drug—no matter how low—and then force a manufacturer to "agree" that the price was "fair," without any meaningful ability to reach a different agreement or to walk away. And a manufacturer would then have no recourse to challenge that price determination, either administratively or through judicial review.

12. The so-called "Drug Price Negotiation Program," therefore, is no negotiation at all. It is a government mandate disguised as negotiation. And it is unconstitutional, on several grounds.

13. ***First***, Congress has impermissibly delegated broad, unconstrained authority to HHS to set prices within Medicare, including between manufacturers and the private prescription drug plans that serve Medicare beneficiaries, in conflict with fundamental separation-of-powers and nondelegation principles. Congress set no meaningful constraints on the agency's exercise of this new price-setting authority. And the harms of that initial structural flaw are compounded further by the other novel and constitutionally suspect features of the program discussed below, all of which serve to avoid accountability. When all the suspect features are considered together, the statute's unconstitutionality is plain.

14. ***Second***, the Program's excise-tax cudgel violates the Eighth Amendment's Excessive Fines Clause. The excise tax aims to force compliance with the sham negotiation scheme by imposing ruinous consequences on any pharmaceutical manufacturer that does not acquiesce. The tax is staggering: Imposed each day that a manufacturer has not expressed "agreement," it increases swiftly to *1,900% of a drug's total revenues*. By design, this tax functions as a penalty. And as a penalty, it is grossly disproportionate to the "offense" it seeks to punish: a manufacturer's unwillingness to agree to a government-mandated price. This penalty will not function as a tax; the Joint Committee on Taxation estimates it will raise literally *zero* revenue, as no rational manufacturer would ever pay it.

15. ***Third***, the Program violates the Fifth Amendment's Due Process Clause by exempting key decisions from public input and insulating them from administrative or judicial review. Unlike virtually any other statutory program affecting the public, the Drug Pricing Program denies manufacturers, providers, and patients the right *both* to front-end input on how the

Program will be implemented *and* to back-end judicial or administrative review after critical implementation decisions have been made. And CMS has proposed to make the process even less transparent by preventing manufacturers from disclosing *any* information about the process by which the agency imposes its price controls. The Program thus deprives pharmaceutical manufacturers of their constitutionally protected property interests—in their patent rights and common-law right to sell their products at market prices free from arbitrary governmental constraints—without affording constitutionally adequate procedural protections. Providers likewise have an interest in receiving the reimbursements to which they are statutorily entitled, as well as to continue operating their businesses and providing treatment to patients, yet the statute provides no adequate procedural protections for those interests either. Patients, affected most personally by the Drug Pricing Program, are deprived of their right to participate in the price-setting process that will determine whether they will continue to have access to potentially life-sustaining or life-extending treatments that they are currently taking or may be prescribed in the future, including those that may never come to the market because of the Drug Pricing Program.

16. In addition to being unconstitutional, the Drug Pricing Program will harm patients, caregivers, physicians, and the broader public interest in pharmaceutical innovation. It will distort the marketplace, inhibit the development of critical new drugs, and disrupt access to needed treatments.

17. For these reasons, and as explained below, Plaintiffs seek a permanent injunction against enforcement of the Drug Pricing Program and excise tax; a declaration that the Drug Pricing Program and excise tax are unconstitutional; a permanent injunction requiring implementation of procedures consistent with due process; a declaration that the procedures enacted by the IRA and implemented by HHS are inadequate; and other appropriate relief.

JURISDICTION AND VENUE

18. This Court has jurisdiction under 28 U.S.C. § 1331 (action arising under the laws of the United States), *id.* § 1346 (United States as a defendant). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 705-06.

19. Venue is proper in this district because this action seeks relief against federal agencies and officials acting in their official capacities, and Plaintiff NICA resides in this district. *See* 28 U.S.C. § 1391(e)(1).

THE PARTIES

20. NICA is a non-profit corporation organized and existing under the laws of the State of Texas, where it also maintains its headquarters. NICA represents non-hospital, community-based infusion providers that allow patients to receive care safely and efficiently in high-quality, lower-cost settings. NICA's efforts are focused on promoting patient safety and care quality, ensuring delivery-channel sustainability and expansion, buy-and-bill protection, maintaining net positive reimbursement, and ensuring that patients have access to viable and sustainable alternatives to hospital care settings. NICA supports policies that improve drug affordability for beneficiaries and reduce disparities in quality of care and safety across care settings.

21. Millions of patients rely on infusion medications to treat diseases like cancer and to manage complex chronic conditions like ulcerative colitis, multiple sclerosis, and lupus. NICA's members operate outpatient facilities to administer these types of treatments, receiving reimbursement from Medicare for services provided to Medicare patients. Currently, these providers generally are reimbursed by Medicare based on the average sales price of the drug and

for some related costs. NICA's members receive significant reimbursement revenue from drugs and treatments that are likely to be included in the IRA's Drug Pricing Program once the Program begins applying to provider-administered drugs under Medicare Part B and Part D. At that point, reimbursement rates for a significant and growing number of the treatments NICA members administer will be based on the IRA's "maximum fair price," and revenues will fall precipitously. NICA expects that these reimbursement changes will cause major revenue decreases for many of NICA's members and that, as a result, a substantial number of NICA's members will have no choice but to scale back operations, to reduce or eliminate the services they provide to Medicare patients, or even to go out of business. Those disruptions in turn will reduce Medicare patients' access to badly needed care. Some patients will to turn to higher-cost hospital care; others will turn to less-effective treatment options; and still others will forgo treatment altogether. The results will be higher costs for Medicare as well as Medicare Part B and Part D beneficiaries.

22. The Global Colon Cancer Association (GCCA) is a non-profit corporation organized and existing under the laws of the State of Delaware, with its headquarters located in Washington, DC. It acts as the voice for the millions of colon cancer patients worldwide by promoting access to quality medical treatments, advocating for patient-centered policy to ensure increased awareness and screening, and helping its member organizations collaborate and innovate. GCCA also supports the creation of new patient advocacy groups in developing areas that have no colon cancer organizations. The vision of GCCA is to create a global community in which people around the world can unite and battle this disease with one unified voice. Colon cancer patients participate directly in GCCA's activities. GCCA maintains a support community of patients and caregivers, mostly in the United States. And over 1,000 colon cancer patients and survivors participated in GCCA's recent Global Colorectal Cancer Congress, an international

gathering dedicated to advancing knowledge, research, and treatment of colorectal cancer. Numerous colon cancer patients rely on drugs that are expected to be subject to the IRA in the first years of implementation, and many more will be harmed by reductions in innovation in developing new drugs and adapting existing drugs to new indications directly and foreseeably caused by the IRA.

23. PhRMA is a non-profit corporation organized and existing under the laws of the State of Delaware, with offices located in Washington, D.C. PhRMA members are the country's leading research-based pharmaceutical and biotechnology companies and are devoted to discovering and developing new medications that allow people to live longer, healthier, and more-productive lives. Since 2000, PhRMA members have invested approximately $1.1 trillion in the search for new treatments and cures, including an estimated $102.3 billion in 2021 alone. PhRMA serves as the research-based pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to advancing public policies that foster continued medical innovation and educating the public about the drug development and discovery process. PhRMA members manufacture many of the most innovative and most widely prescribed medicines in America that are recognized as the standard of care for the conditions they treat. Many of those drugs are widely used by patients treated under Medicare Part B and Part D; because of their success and widespread use, they are the among the most widely reimbursed under those programs. Accordingly, PhRMA members manufacture and sell most of the single source drugs that are subject to the statutory provisions challenged here. A list of PhRMA members can be found at www.phrma.org.

24. PhRMA members manufacture drugs that will be selected for the Drug Pricing Program under the IRA for 2026. The drugs that, based on HHS's announced criteria, will be selected for 2026 are listed in the margin, and nine out of ten are manufactured by PhRMA members.[1]

25. Defendant HHS is an executive department of the United States Government headquartered in Washington, D.C. HHS is responsible for administering the Medicare program and the relevant statutory provisions challenged here.

26. Defendant Xavier Becerra is the Secretary of HHS. He oversees the Medicare program, among other things, and is responsible for administering the relevant statutory provisions challenged here. He is sued in his official capacity.

27. Defendant the Centers for Medicare and Medicaid Services (CMS) is an administrative agency within HHS that is headquartered in Baltimore County, MD, and that administers the Medicare program.

28. Defendant Chiquita Brooks-LaSure is the CMS Administrator. She administers the IRA's Drug Pricing Program under authority delegated by the Secretary. She is sued in her official capacity.

BACKGROUND

Pharmaceutical Innovation Depends on Investment in Research and Development

29. PhRMA's members discover and develop life-saving and life-enhancing medicines that are distributed, prescribed, and used across the nation and around the world. Between 2000

[1] Eliquis, Xarelto, Januvia, Jardiance, Imbruvica, Novolog, Xtandi, Enbrel, Myrbetriq, and Spiriva.

and 2021, the FDA approved nearly 800 new drugs. Asher Mullard, *2021 FDA Drug Approvals*, 21 Nature 83, 83 fig.1 (Feb. 2022), https://bit.ly/40uv3XT. PhRMA's members were responsible for much of this innovation and the R&D that make them possible. For example, total U.S. biopharmaceutical industry R&D was estimated at $122 billion in 2020, while PhRMA's annual member survey shows that PhRMA members collectively invested $91 billion in R&D in that year.

30. As biopharmaceutical companies build on new technologies and advances in scientific knowledge, they continue to develop groundbreaking therapies for devastating diseases afflicting patients. Pharmaceutical researchers are currently researching and developing a wide array of therapies, including over 700 medicines to treat rare diseases; 200 medicines for cancers that primarily affect women, 119 of which are for breast cancer; 549 medicines targeting blood disorders; and nearly 600 cutting-edge medicines to meet the unique needs of pediatric patients. *See* PhRMA, *Medicines in Development 2021 Report: Rare Diseases* 1 (Dec. 2021), https://bit.ly/3go50j8; PhRMA, *Medicines in Development 2022 Report: Women* 2 (Mar. 2022), https://bit.ly/3EzupyG; PhRMA, *Medicines in Development 2022 Report: Disorders of the Blood* 2 (May 2022), https://bit.ly/3TWI9Jn; Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Report: Children* 1 (Jan. 2020), https://onphr.ma/2PSX4FN.

31. Pharmaceutical companies are also working on more than 350 novel cell and gene therapies, including nearly 200 that treat various forms of cancer. *See* Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Update: Cell and Gene Therapy* 1–2 (Feb. 2020), https://onphr.ma/3fY6wSX. One of the most promising areas of development is immuno-oncology, which aims to harness the body's own immune system to fight cancer. *See* Sophie Carter & David E. Thurston, *Immuno-Oncology Agents for Cancer Therapy*, Pharm. J. (May 7, 2020), https://bit.ly/3XfwicG. Recent discoveries and clinical advances in the area have already begun

improving outcomes and survival rates for some patients, including those with skin, kidney, and lung cancer. *See id.* The objective is to supplement or even replace chemotherapy as the first-line treatment for many cancers and thereby improve both outcomes and the patients' experience. *See id.*

32. Pharmaceutical companies are similarly developing cutting-edge treatments for Alzheimer's Disease, with years of research recently leading to an entirely new class of therapies for the disease. *See* PhRMA, *Continued Progress Toward New Treatments for Alzheimer's Disease Provides Hope to Millions* 1 (Mar. 2022), https://onphr.ma/42zq8pt. But that progress did not come easily. It built upon 198 unsuccessful attempts in clinical trials between 1998 and 2021 alone. *Id.* Alzheimer's is a devastating illness that disproportionately affects the elderly, women, and people of color. PhRMA, *Researching Alzheimer's Medicines: Setbacks and Stepping Stones* (May 2021), https://bit.ly/3W0Kh5m. There are significant challenges in developing medicines for Alzheimer's, but "[a]s the aging population grows, so does the need to . . . address this disease." *Id.*

33. The cost of developing such groundbreaking drugs is stunning. On average, a manufacturer will spend nearly $3 billion developing one new medicine. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25–26 (2016), https://bit.ly/30UAIdg. Some pharmaceutical companies have invested an average of over $10 billion per new drug. *See* Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med., no. 105, 2016, at 3–4, https://bit.ly/2PWRKRC. And research and development costs do not end at FDA approval; pharmaceutical manufacturers often undertake significant post-approval research as well, to help further ensure safety and efficacy and to refine drugs and their delivery systems to meet patient

needs. *See* Andrew Powaleny, *3 Things to Know About the Importance of Post-Approval Research and Development*, PhRMA (Dec. 6, 2021), https://bit.ly/3upKkut.

34. Manufacturers developing new drugs face incredibly long odds. Only one compound in 5,000 that enters preclinical testing will achieve FDA approval, for a failure rate of 99.98%. Sandra Kraljevic et. al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://bit.ly/2Y2gwEK. Of the therapies approved for patient use, only one-third manage to cover their cost of development, much less to provide an economic return significant enough to allow for continued investment and innovation. *See* Vernon & Golec, *supra*, at 7.

35. Moreover, the required investments in time and expense to research and develop innovative new drugs are continually increasing. It now takes an average of ten to fifteen years to develop a single drug. *See* DiMasi et al., *supra*, at 25–26. And over the last 60 years, research and development costs in the pharmaceutical industry have increased 8.6% annually, even after adjusting for inflation. Schuhmacher et al., *supra*, at 3. One study found that from 2003 to 2013, the cost of developing a prescription drug that gains approval soared 145%. *See* DiMasi et al., *supra*, at 28. These increased development costs result from a variety of factors: Clinical drug development takes more time as the necessary research grows more complicated; the drugs themselves (especially biologics) are becoming more complex; and demands by regulatory authorities and payers are escalating. *See* Schuhmacher et al., *supra*, at 4, 6.

36. At the same time, other factors have reduced the returns on the drugs that *are* approved for patient use. For example, treatments are becoming increasingly personalized, taking into consideration a patient's "genetic, anatomical, and physiological characteristics." U.S. Dep't of Health & Human Servs. & U.S. Food & Drug Admin., *supra*, at 4. In 2021, for instance, FDA

approved 17 personalized medicines with specific biological markers to help guide prescribers' decisions, representing 35% of all FDA-approved therapeutic products that year. Personalized Med. Coal., *Personalized Medicine at FDA: The Scope & Significance of Progress in 2021*, at 3 (2022), http://bit.ly/3NWTvf3; *see id.* a 2 ("Personalized medicines have now accounted for more than a third of new drug approvals for four of the last five years."). These drugs are often critical in treating serious but rare illnesses, yet their targeted nature both increases development costs and reduces the patient population that can help to defray those up-front costs.

37. In short, the task facing most pharmaceutical companies is staggering. They must risk billions of dollars to research, discover, and test compounds, *only 0.02%* of which will ever reach patients, and only a further third of which—0.0067%—will ever recoup their development costs. Paul Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538 (2021), https://bit.ly/3NF5LSY.

38. Pharmaceutical manufacturers therefore must make these high-risk investments based on an uncertain prospect—that *if* they discover a compound, *if* it can be made into a drug that proves safe and efficacious, *if* it obtains regulatory approval, and *if* it reaches patients and fulfills a medical need, the product *might* earn market-based returns.

39. Medical providers, including members of NICA, also depend on pharmaceutical innovation and will suffer severe harm from the IRA. Providers are in the business of extending and improving patients' lives by providing them with treatment—including in the form of new drugs and therapies. Administering innovative drugs and biologics and obtaining reimbursement based on market prices is the foundation of how providers serve the needs of their patients and keep their doors open.

40. Patients, including those represented by GCCA, most directly depend on pharmaceutical innovation to save or extend their lives, or to improve their quality of life. Patients' desire to access more-effective drugs with fewer side effects drives pharmaceutical innovation.

Medicare Has Traditionally Encouraged Pharmaceutical Innovation

41. Manufacturers and providers invest enormous sums in pharmaceutical innovation, making it possible for Americans to access and benefit from the most-advanced treatment options available. Manufacturers generally obtain approval for and market new drugs in the United States first; other countries depend on (and eventually benefit from) U.S.-funded pharmaceutical innovation and development. *See* Doug Badger, *Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access* 15 (2019), http://bit.ly/3E4A7bz (finding that the United States has access to 89% of new active substances that became available between 2011 and 2018, while certain developed countries with pharmaceutical price controls had, on average, access to less than 50%); PhRMA, *Global Access to New Medicines Report* 8, 11–36 (Apr. 2023) (finding that new medicines generally launch first and fastest in the United States as compared to other countries). By contrast, foreign countries with drug price controls have, as a consequence, experienced drastic decreases in domestic pharmaceutical research, investment, and development. *See* John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 4 (2008); Joe Kennedy, *The Link Between Drug Prices and Research on the Next Generation of Cures*, Info. Tech. & Innovation Found. (Sept. 9, 2019), https://bit.ly/3fSIysc; Taylor T. Schwartz et al., *The Impact of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health*, ISPOR (May 2018), https://bit.ly/3ar7HJB; Dana Goldman & Darius Lakdawalla, Leonard D. Schaeffer Ctr. for Health Pol'y & Econ., Univ.

of S. Cal., *The Global Burden of Medical Innovation* 4 (Jan. 2018), https://bit.ly/34dtzXR. And advanced treatments are often delayed in reaching those countries, if those treatments are available to their citizens at all. *See* PhRMA, *Global Access to New Medicines Report* 8, 11–36 (Apr. 2023).

42. Drug reimbursement under Medicare Part B traditionally has encouraged American innovation. Medicare Part B covers a wide range of healthcare services for its beneficiaries, including primarily drugs administered by a physician. *See* 42 U.S.C. § 1395k(a)(1); *id*. § 1395x(s)(2)(A). Congress has long required Medicare Part B to reimburse in most cases at the drug's "average sales price"—a market-based figure that reflects the volume-weighted quarterly average of all manufacturer sales prices to U.S. purchasers (with limited exceptions), increased by a specified percentage. By basing Part B payments on market transactions, Congress provided pharmaceutical companies the opportunity to earn competitive returns that encourage and fund future innovation.

43. Congress similarly adopted market-based mechanisms for Medicare Part D, which covers self-administered drugs. Indeed, when Congress created Part D, *see* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066, it included a provision expressly *prohibiting* HHS from "interfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the price of Part D drugs. 42 U.S.C. § 1395w–111(i).

The Inflation Reduction Act Ignores the Economic Realities of Drug Development and Will Stifle Innovation

44. When Congress enacted the Inflation Reduction Act of 2022, it upended the market-based system that has long made America the world leader in pharmaceutical innovation. The IRA establishes a so-called "Drug Price Negotiation Program" for setting Medicare drug prices. But in fact, the Program involves no genuine negotiation at all. Rather, the law creates a sham process to

create the false impression that manufacturers are "agreeing" to a "maximum fair price" for their products—when, in reality, HHS is imposing these price controls by administrative *fiat*. Under the IRA, the agency compels manufacturers to "agree[]" to prices the agency chooses, under threat of a crippling "excise tax"—amounting to astonishing multiples of the manufacturer's *total U.S. revenues* for the drug—which is designed to ensure obedience. The law also leaves affected manufacturers without meaningful voice or recourse: Manufacturers have virtually no ability to effectively counter HHS's position; HHS need not solicit public comment regarding key aspects of the Program's implementation during its formative years; and many of HHS's critical implementation decisions are *never* subject to administrative or judicial review.

HHS Selects "Negotiation-Eligible Drugs"

45. Rather than setting prices itself—or even identifying the affected drugs—Congress delegated that work to HHS. The IRA directs HHS to establish a "Drug Price Negotiation Program." 42 U.S.C. § 1320f(a). Beginning in 2023, HHS must rank single-source "negotiation-eligible drugs" based upon HHS's "total expenditures" under Medicare (first in Part D and then in both Part B and Part D) over a previous twelve-month period. *Id.* § 1320f–1(b)(1)(A). The drugs involving the highest total expenditures during that period are to be ranked the highest. *Id.* § 1320f–1(b)(1)(B).

46. The IRA defines "negotiation-eligible drugs" to include certain "qualifying single source drugs," which encompass many of the most innovative drug products and biological products. *Id.* § 1320f–1(d)(1), (e)(1). For drug products, a qualifying single source drug is one that (1) is marketed under a new drug application pursuant to 21 U.S.C. § 355(c); (2) has been approved by FDA for at least seven years; and (3) is not the reference listed drug for a generic drug marketed under an abbreviated new drug application pursuant to 21 U.S.C. § 355(j). 42 U.S.C. § 1320f–

1(e)(1)(A). For biological products, a qualifying single source drug is one that (1) is marketed under a biologics license application pursuant to 42 U.S.C. § 262(a); (2) has been licensed by FDA for at least 11 years; and (3) is not the reference product for any biosimilar product marketed under 42 U.S.C. § 262(k). *Id.* § 1320f–1(e)(1)(B).[2]

47. Importantly, HHS has interpreted the IRA to give the agency unfettered discretion to make basic policy choices. For example, HHS has asserted discretion over determining when multiple products may constitute a single "qualifying single source drug[]," such that their total expenditures are summed together for purposes of the HHS rankings. HHS also has asserted discretion over what it means for a generic drug or biosimilar product to be "marketed," such that the reference drug or biological product is not a qualifying single source drug or must be removed from the selected drug list.

48. Furthermore, while the IRA includes a statutory definition of "total expenditures," that definition still affords HHS wide discretion. For Part D, the IRA defines "total expenditures" as "includ[ing] … total gross covered prescription drug costs" as defined in the Part D statute. *Id.* § 1320f(c)(5). But the Part D statute defines that term for an entirely different purpose, and the definition is sufficiently open-ended that HHS has substantially revised the definition *since the IRA was enacted*. *See* 88 Fed. Reg. 22,120, 22,260 (Apr. 12, 2023) (revising definition to "reflect gross costs, not net costs"). For Part B, the definition of "total expenditures" is even less definite—the IRA provides that total expenditures for Part B drugs "excludes" certain expenditures that are "bundled or packaged into the payment for another service," but it does not specify at all what that term *includes*. 42 U.S.C. § 1320f(c)(5).

[2] The IRA excludes certain drugs from negotiation eligibility, including "[c]ertain orphan drugs," "[l]ow-spend medicare drugs," and "[p]lasma-derived products." 42 U.S.C. § 1320f–1(e)(3). Under certain circumstances, the IRA also authorizes HHS to delay selection and negotiation of biologic drugs that have been on the market for 12–16 years. *See id.* § 1320f–1(f).

49. Once "negotiation-eligible" drugs have been ranked, the IRA directs HHS to select an increasing number of the highest-ranked drugs for negotiation. Part D drugs will be selected for negotiation starting in 2023, with the first set of maximum fair prices for Part D drugs taking effect beginning in 2026; Part B is added to the selection process beginning in 2026, with maximum prices taking effect in 2028. *Id.* §§ 1320f–1(a)(1), 1320f–1(b)(1)(A), 1320f–1(a)(3)–(4). Ten Part D drugs will be selected for 2026, fifteen Part D drugs for 2027, fifteen Part D and Part B drugs for 2028, and twenty Part D and Part B drugs for 2029 and each year thereafter. *Id.* § 1320f–1(a)(1)–(4). This drug-selection process is cumulative: Once a drug is selected, it remains selected until HHS determines that a generic or biosimilar version of the drug is approved or licensed and marketed pursuant to that approval. *Id.* § 1320f–1(c)(1). The number of drugs subject to the Program thus mounts over time. It is expected that, within ten years, *half* of all Medicare drug spending will be for drugs whose price is set under this program.

The IRA Grants HHS Unfettered Discretion to Set "Maximum Fair Prices" Through Sham "Negotiations"

50. Once innovative drugs are ranked and selected for negotiation, the IRA directs HHS to "enter into agreements" with manufacturers to set a "maximum fair price" (MFP) for the selected drugs. *Id.* § 1320f–2(a)(1). But these documents are not "agreements" in any meaningful sense; they are coerced through a sham negotiation process that bears no resemblance to any ordinary commercial negotiation. And the "negotiated" MFP of a drug is just a government-imposed price control, subject to a statutory ceiling but—with one narrow, time-limited exception—no floor. *Id.* § 1320f–3(c); *see id.* § 1320f–3(b)(2)(F)(ii) (creating temporary floor only for certain small biotech manufacturers).

51. The IRA directs HHS to "develop and use a consistent methodology and process . . . for negotiations . . . that aims to achieve the *lowest* maximum fair price for each selected drug."

Id. § 1320f–3(b)(1) (emphasis added). The process purports to resemble a commercial negotiation but in reality is nothing of the kind. It includes an HHS "offer," a manufacturer "counteroffer," and an HHS response. *Id.* § 1320f–3(b)(2)(C)–(D). But that is where the resemblance to genuine negotiation ends.

52. Unlike in a commercial negotiation, the government can demand whatever information it wants on pain of massive daily fines. Manufacturers must turn over a host of closely guarded proprietary and trade secret information to HHS, such as the manufacturer's research and development costs, market data for the drug, and costs of production and distribution. *Id.* § 1320f–2(a)(4)(B), (e)(1). Moreover, manufacturers must "compl[y] with" whatever *other* requirements HHS unilaterally imposes as "necessary for purposes of administering the program," *id.* §§ 1320f–6(c), 1320f–2(a)(5), without even having any opportunity to comment before those requirements are imposed. *See infra*, ¶ 68. And manufacturers must provide all that information under the threat of $1 million-per-day penalties for each day before they respond. *Id.* §§ 1320f–2(a)(4)-(5), 1320f–6(c).

53. As far as the substance of the "agreement," the law does not limit how low a price HHS can demand, nor does it provide a clear standard for the agency to use in setting prices. But it does impose caps on how *high* a price HHS can set. The caps are designed to yield a low ceiling price, directing HHS to use as the ceiling the lowest number yielded by various alternative calculations specified by statute. As an example of the sorts of minimum discounts contemplated, one alternative calculation is based on an initial baseline price that is itself lower than the manufacturer's wholesale price—ranging from 75% of that initial baseline for more recently approved drugs, to just 40% for drugs that have been approved for 16 or more years. *Id.* §§ 1320f–3(c)(1)(C), 1320f–3(b)(2)(F). The Act says that HHS "shall consider" a variety of statutory factors,

including research and development costs, unit costs, prior federal financial support, data on pending and approved patent applications, market data and revenue and sales volume data, and information about alternative treatments. *Id.* § 1320f–3(e). Yet it sets no criteria regarding how HHS is to weigh those factors. Nor does it set criteria regarding HHS's "offers," or the bases upon which HHS may reject a manufacturer's "counteroffer," except to say that HHS may *not* accept any counteroffer that exceeds the statutory ceiling. *Id.* § 1320f–3(b)(2)(F). Indeed, the Act creates no mechanism to ensure HHS creates a non-arbitrary process or consistently follows it.

54. Moreover, the IRA restricts a manufacturer's ability to "counteroffer," dictating that a manufacturer "shall" justify its counteroffers only on certain specified factors: research and development costs, and the extent to which they have been recouped; current production and distribution costs; prior federal financial support for development; data on pending and approved patent applications; market data and revenue and sales volume data for the drug; and certain evidence regarding alternative treatments. *Id.* §§ 1320f–3(b)(2)(C)(ii), 1320f–3(e). Accordingly, unlike in commercial negotiations, manufacturers cannot make a counteroffer on the ground that revenue for an existing drug is needed to fund research into other drugs, or simply on the ground that the manufacturer believes that its product is worth more than was initially offered.

55. Even more egregiously, the IRA requires manufacturers to "enter into an agreement" to accept whatever "maximum fair price[s]" HHS has chosen for the manufacturers' products. *Id.* §§ 1320f–2(a), 1320f–3(a). If they do not, they must pay a cripplingly high and rapidly escalating "excise tax," 26 U.S.C. § 5000D(b), which will be discussed further below. In other words, on the face of the law, manufacturers have no choice but to voice their assent to whatever price HHS ultimately demands. If they do not, they will be dealt massive penalties.

56. Once HHS has imposed an MFP for a selected drug, the statute provides that the manufacturer must provide "access to such price to" a wide variety of individuals and entities participating in Medicare. 42 U.S.C. § 1320f–2(a)(1). These include all eligible individuals who are dispensed drugs under Medicare Parts B and D; all "pharmacies, mail order services, and other dispensers" that dispense drugs to Medicare beneficiaries; and all "hospitals, physicians, and other providers of services and suppliers" that furnished or administered drugs to Medicare beneficiaries. *Id.* § 1320f–2(a)(1)(A)–(B); *see id.* § 1320f(c)(2). But the statute contains no mechanism to ensure that MFP prices are made available only with respect to eligible patients. Manufacturers that fail to provide the required access to the MFP are subject to a civil monetary penalty of *ten times* the difference between the price the manufacturer actually makes available and the MFP, multiplied by the total number of units sold. *Id.* § 1320f–6(a).

HHS Enforces the Sham Negotiations Through a Crippling "Excise Tax"

57. The hammer through which the Drug Pricing Program is enforced is the so-called "Excise Tax Imposed on Drug Manufacturers During Noncompliance Periods." IRA § 11003. In actual negotiations, of course, parties that fail to reach mutually agreeable terms do not finalize a deal and can simply walk away. Under the IRA, by contrast, a manufacturer that refuses to accede to the price HHS demands for one of the manufacturer's products cannot just walk away. Instead, it must pay a crippling penalty, amounting to multiples of *all* sales of the drug, both in the Medicare program and outside of it.

58. Here is how it works. A manufacturer that fails to "agree" to a price is subject to an escalating penalty. 26 U.S.C. § 5000D(b). This penalty is disguised as an excise tax: Congress codified it in the portion of the Internal Revenue Code governing "Miscellaneous Excise Taxes."

The penalty continues to accrue every day until the manufacturer enters into an "agreement" with HHS (or the drug in question ceases to be negotiation-eligible).

59. The daily penalty is calculated based on a formula for an "applicable percentage," which starts at 65% and increases by 10% for each successive quarter the manufacturer is out of compliance, to a maximum of 95%. *Id.* § 5000D(d). The statute provides that the penalty is "in an amount such that the applicable percentage is equal to the ratio of (1) such tax, divided by (2) the sum of such tax and the price for which so sold [*sic*]." *Id*. § 5000D(a).

60. The tax can be calculated by setting the statutory formula equal to the "applicable percentage" and then solving for the tax:

$$\text{applicable percentage} = \frac{\text{tax}}{(\text{tax} + \text{sales price of drug})}$$

For example, using the highest "applicable percentage" (95%), one would solve for the excise-tax penalty as follows:

$$\textbf{STEP 1}: .95 = \frac{\text{tax}}{(\text{tax} + \text{sales price of drug})}$$

$$\textbf{STEP 2}: \text{tax} = .95\ (\text{tax} + \text{sales price of drug})$$

$$\textbf{STEP 3}: \text{tax} = .95\ (\text{tax}) + .95\ (\text{sales price of drug})$$

$$\textbf{STEP 4}: \text{tax} - .95(\text{tax}) = .95\ (\text{sales price of drug})$$

$$\textbf{STEP 5}: .05(\text{tax}) = .95\ (\text{sales price of drug})$$

$$\textbf{STEP 6}: \text{tax} = \frac{.95\ (\text{sales price of drug})}{.05}$$

$$\textbf{SOLUTION}: \text{tax} = 19\ (\text{sales price of drug})$$

The penalty applies to *each sale* of the subject drug, not merely to Medicare sales. *See id*. As the Congressional Research Service has explained, the statutory formula yields a staggering maximum daily penalty equal to *19 times* the drug's daily sales revenue. *See* Cong. Rsch. Serv., *Tax*

Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) 4 tbl. 2 (2022). Even using the lowest applicable percentage in the formula (65%), the daily penalty starts at approximately 186% of—nearly double—the manufacturer's daily sales revenue from the drug. *See id.* ("The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance."). Thus, the excise-tax penalty represents a multiple of the manufacturer's *total revenues* from the drug in question. A title summary of the predecessor legislation accurately described this as a "steep, escalating penalty" imposed on manufacturers who do not "agree to" the price HHS unilaterally selects. *See* Title Summary at 1, H.R. 3 (2022).

61. In practice, of course, the crippling excise-tax penalty prevents manufacturers from doing anything but acquiescing to whatever price HHS demands. But the penalty also shapes the prices that HHS can foist upon manufacturers through the statute's sham "negotiation" process. HHS could, for example, decide to approach the "negotiations" by making a best and final "offer" that would impose serious financial losses on a manufacturer. Yet manufacturers would have no choice but to accept even a massive reduction in Medicare prices, rather than incur a nineteen-fold penalty on all sales of the drug.

62. Congress well understood that, in practice, the threat of this ruinous excise tax would force manufacturers to accept whatever price HHS demands. The Joint Committee on Taxation estimated that an essentially identical excise-tax provision in predecessor legislation would raise "no revenue" whatsoever, because no manufacturer could possibly afford to pay it; instead, manufacturers will be forced to "agree" to HHS's chosen maximum "fair" price. Joint Comm. on Tax'n, *Estimated Budget Effects of the Revenue Provisions Of Title XIII - Committee On Ways And Means, of H.R. 5376, The "Build Back Better Act," As Passed by the House Of Representatives, Fiscal Years 2022–2031*, at 8 (Nov. 19, 2021), https://bit.ly/3plC4cd ("no

revenue effect"); *accord* Letter from P.L. Swagel, Director, Congressional Budget Office, to Hon. F. Pallone Jr., Chairman, Committee on Energy and Commerce (Oct. 11, 2019), at 14, *available at* https://bit.ly/3osZPzX.

63. The IRA provides for the "[s]uspension" of the punitive excise-tax penalty, but only if the manufacturer terminates its Medicare Part D agreements and Medicaid rebate agreement—not just for the drug in question, but for *all* of the manufacturer's drugs. 26 U.S.C. § 5000D(c); *see id.* § 5000D(c)(1). Terminating the Medicaid rebate agreement would also result in all of the manufacturer's products losing Part B coverage, because for a drug to be payable under Part B, "the manufacturer must have entered into and have in effect a [Medicaid] rebate agreement." 42 U.S.C. § 1396r-8(a)(1). Thus, a pharmaceutical manufacturer must entirely cease participation in both Medicare and Medicaid in order to suspend application of the tax penalty.

64. But the IRA constrains manufacturers from taking even that drastic step: The Act expressly delays a manufacturer's ability to exit from Part D—and thus compels them to participate in it—*for between 11 and 23 months*. *See id.* § 1395w-114a(b)(1)(C)(ii); *id.* § 1395w–114c(b)(4)(B)(ii); *id.* § 1395w–153(a)(1). If a manufacturer's Part D drugs were selected for forced "negotiation" during this period, then the manufacturer would have no choice but to acquiesce to HHS's chosen "maximum fair price" or pay the crippling excise tax until it is finally permitted to leave the program. *See* 26 U.S.C. § 5000D(c)(1). Indeed, to exit Part D in time to avoid being penalized for failing to sign an "agreement" for 2026 by the statutory deadline of October 1, 2023, *see* 42 U.S.C. § 1320f-2(a), a manufacturer would have had to provide a termination notice to HHS by January 29, 2022—months before the IRA was even enacted into law. And that termination would exclude all of the manufacturers' products from coverage under Part D indefinitely starting in 2023—years before the actual price controls would take effect in 2026.

The IRA Exempts Key Decisions from Public Input and Insulates Them from Administrative or Judicial Review

65. Pharmaceutical manufacturers face serious burdens from the IRA's faux negotiation process and mandatory price controls. They must sell their products at government-controlled prices, reevaluate the viability of their entire pipeline of products in development, and reduce and reallocate their research and development spending.

66. Providers face similarly serious burdens. For example, NICA's infusion-center members currently earn margins of approximately 0-4% when providing infusion treatments to Medicare patients, who make up 30-60% of their patients. But the vast majority of Medicare reimbursements that NICA's members receive come from reimbursements for the drugs themselves (as opposed to reimbursements for infusion service charges). If the prices for those drugs are subject to an arbitrary ceiling, the margins that NICA members earn on those drugs will decrease, causing them to incur losses on services to Medicare patients. NICA members then will face a choice between cutting back or eliminating services for Medicare patients or going out of business. The end result in either scenario will be to force Medicare patients to receive infusion services in higher-cost hospital settings, while harming NICA's members—which provide infusion services at a lower overall price point.

67. Despite these burdens, manufacturers, providers, patients, and other affected parties are given no say in how HHS decides to implement the program, and they are deprived of legal recourse regarding numerous critical decisions.

68. On the front end, there is no right to participate in the implementation process. The Administrative Procedure Act sets forth general procedural requirements for agency rulemaking, including provisions requiring the agency to publish a notice of proposed rules in the Federal Register and to give interested persons an opportunity to submit written comments, which the

agency in turn must consider. 5 U.S.C. § 553(b), (c). And the Social Security Act requires HHS to follow those procedural requirements when engaging in substantive rulemaking in Medicare. *See* 42 U.S.C. § 1395hh. The IRA, however, provides that HHS "shall implement this section, including the amendments made by this section, for 2026, 2027, and 2028, by program instruction or other forms of program guidance." IRA §§ 11001(c), 11002(c). And CMS has interpreted that language to mean that implementation "is not subject to the notice-and-comment requirements of the Administrative Procedure Act or the Medicare statute." *See* Ctr. for Medicare, Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments 2 (March 15, 2023) (Initial Guidance). In other words, according to the agency, the statute contemplates that the implementation of this groundbreaking new drug price pricing program need not go through any notice-and-comment rulemaking process *at least through 2028*, including the program's most formative years. Even after that point, the IRA itself does not provide *any* mechanism for affected persons or entities—including pharmaceutical manufacturers that will be subject to price controls and providers that will have their reimbursement rates slashed—to observe, comment on, or contribute to the process through which HHS decides what prices to impose. Manufacturers do not even have any right to have a say in requirements that HHS may unilaterally impose and then seek to enforce through a $1 million-per-day fine.

69. On the back end, the IRA insulates critical implementation decisions from review. It provides that "[t]here shall be no administrative or judicial review" of a number of HHS's key determinations, including "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "[t]he determination of a maximum fair price under [the Act]." 42 U.S.C. § 1320f–7(2)–(3). Taken literally, this provision

would preclude administrative or judicial review of some of the most critical determinations under this new program.

70. While these provisions limiting front-end public comment and back-end administrative and judicial review are unusual in isolation, in combination they are nothing short of extraordinary. NICA, GCCA, and PhRMA are not aware of any other statute that comprehensively bars *all* external input into and review of an agency decision-making process that will have such profound effects on the public—to the point of upending the finances of an entire critical industry. These provisions deprive stakeholders—including pharmaceutical manufacturers, medical providers, and their patients—of all possible procedural safeguards regarding important implementation decisions before they are made and once they are in place.

The IRA's Novel Structure Violates Fundamental Nondelegation and Separation-of-Powers Principles

71. Article I, section 1 of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." As Chief Justice Marshall explained, that provision means that Congress may not "delegate to [other branches] powers which are strictly and exclusively legislative." *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42 (1825). Indeed, "[t]hat congress cannot delegate legislative power to the [executive branch] is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the constitution." *Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1892). The Supreme Court has twice struck down statutes as violating these principles. *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Panama Ref. Co. v. Ryan*, 293 U.S. 388 (1935). The Fifth Circuit recently has done so as well. *See Jarkesy v. SEC*, 34 F.4th 446, 459-63 (5th Cir. 2022). As the Supreme Court has unanimously reiterated, Congress may not "transfer[] its legislative power to another branch of Government." *Gundy v. United States*, 139 S. Ct. 2116, 2121 (2019) (plurality

op.); *see id.* at 2130 (Alito, J., concurring in the judgment) (similar); *id.* at 2133-35 (Gorsuch, J., dissenting) (similar). And in evaluating a statute's compliance with the nondelegation doctrine, the availability of "judicial review" and "mandated compliance with . . . requirements for notice and comment" are relevant factors. *United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (citation omitted).

72. The nondelegation doctrine accords with larger separation-of-powers principles. The Framers "split the atom of sovereignty itself into one Federal Government and the States," and "then divided the powers of the new Federal Government into three defined categories, Legislative, Executive, and Judicial." *Seila L. LLC v. CFPB*, 140 S. Ct. 2183, 2202 (2020) (quotation marks omitted). "The resulting constitutional strategy is straightforward: divide power everywhere except for the Presidency, and render the President directly accountable to the people through regular elections." *Id.* at 2203. Congress "contravenes this carefully calibrated system" if it "vest[s] significant governmental power in the hands of a single individual accountable to no one." *Id.*; *see Cmty. Fin. Servs. Ass'n of Am., Ltd. v. CFPB*, 51 F.4th 616, 640 (5th Cir. 2022), *cert. granted*, 143 S. Ct. 978 (2023) (similar). And "'[p]erhaps the most telling indication of [a] severe constitutional problem' with an executive entity 'is a lack of historical precedent' to support it." *Seila L.*, 140 S. Ct. at 2201 (quoting *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505 (2010)).

73. The price control scheme Congress established in the IRA is entirely novel.

74. In the past, when Congress wished to displace market mechanisms in favor of agency-set prices, it has followed a well-established path: clearly specifying a substantive legal standard by which the agency is to set rates, imposing appropriate procedural safeguards to protect the interests of the regulated parties and ensure pricing meets the needs of the public, and providing

for appropriate judicial review. *See*, *e.g.*, 15 U.S.C. §§ 717c, 717r; 16 U.S.C. §§ 824d, 824e; 39 U.S.C. § 3622.

75. Instead of following that established course, Congress took a different, novel, and *unconstitutional* path in the IRA: Congress delegated unfettered discretion to HHS to set prices however it wishes.

76. To begin with, while the Act directs the agency to consider certain "factors" when setting prices, 42 U.S.C. § 1320f–3(e), it provides no guidance whatsoever about how the agency should weigh those factors and sets no concrete limits on the agency's ultimate discretion to choose prices. At most, the statute sets a ceiling price the agency must not exceed, *see* 42 U.S.C. § 1320f-3(b)(2)(F), (c), while directing HHS to "develop and use a consistent methodology and process . . . that aims to achieve the *lowest* maximum fair price," *id.* § 1320f–3(b)(1) (emphasis added). In effect, HHS has been given the open-ended task of replacing market prices for Medicare's highest-spend drugs with an entirely new set of prices that can go as low as the agency chooses.

77. Furthermore, key terms of the IRA are sufficiently open-ended to allow HHS to claim authority to make fundamental policy choices. For example, at least as HHS reads it, the statute does not specify whether and when multiple products qualify as a single negotiation-eligible drug, such that their separate total expenditures are counted together for purposes of HHS's rankings. HHS likewise reads the statute not to specify what it means for a generic drug or biosimilar product to be "marketed," such that the reference drug or biological product would not be eligible for selection or would be removed from the selected drug list. And HHS has asserted wide discretion regarding what expenditures are included in and excluded from the "total expenditures" that determine the rankings. *See supra*, ¶ 47. This claimed discretion leaves HHS with the authority to make key substantive

decisions regarding not only which drugs are negotiation eligible, but also for how long selected drugs remain subject to MFP negotiation.

78. At the same time, the Act includes no safeguards to protect the interests of manufacturers, providers, patients, or the public. The Act does not require HHS to undertake notice-and-comment rulemaking, or even to solicit external input at all. And the draconian excise tax virtually guarantees that manufacturers have no way to protect their interests or resist arbitrary agency decision-making. Punitive in nature and wildly disproportionate to the conduct it seeks to punish, the tax further aggrandizes HHS's power, ensuring that no manufacturer will be able to resist even the agency's most extortionate price controls. *See infra*, ¶¶ 93–104.

79. Finally, the Act seeks to insulate many of the most important implementation decisions from any judicial review. *See* 42 U.S.C. § 1320f–7. This bar on all back-end judicial review of key implementation decisions raises particularly acute separation-of-powers concerns. Permitting an agency to resolve basic interpretive questions regarding a statute it administers without *any* possibility of judicial review is the equivalent of permitting an agency to rewrite those statutory provisions—a wholly legislative function. After all, the agency could adopt, implement, and enforce a reading of the statute that was clearly contrary to the text and Congress's intent, and then attempt to claim that no administrative or judicial review is available to correct the agency's overreach.

80. At the extreme, HHS could—with complete impunity—willfully ignore one of the few binding constraints the statute imposes on its new price-setting authority. For example, even though the statute provides that a drug product is not a qualifying single source drug unless it has been approved by FDA for seven years, *see* 42 U.S.C. § 1320f–1(e)(1)(A), HHS could decide to ignore that requirement, selecting a blockbuster drug for negotiation after just one year because,

in the agency's view, expenditures for that drug were particularly high. The manufacturer then could try to challenge that patently unlawful decision in court, but HHS could cite the IRA's judicial review bar, which provides that "[t]here shall be no administrative or judicial review" of "[t]he selection of drugs" or "the determination of qualifying single source drugs." 42 U.S.C. § 1320f–7(2)–(3). And this is just one example—HHS could ignore many other clear-cut statutory requirements and still claim that the statute insulates the agency's lawlessness from any outside review.

81. Each of these defects, standing alone, violates bedrock constitutional principles. But taken together—and especially in combination with several other, equally flawed provisions—the IRA's novel structure concentrates substantial power over a significant part of the economy in an administrative agency with no checks to ensure public accountability. That combination is fatal to the Act.

82. These dangers are not just theoretical—CMS has already begun to exercise the full extent of its immense authority to define the parameters of the Drug Pricing Program with no opportunity for input or review. On March 15, 2023, CMS issued initial guidance regarding implementation of the IRA's drug selection and pricing scheme. *See* Initial Guidance. The Initial Guidance's stated purpose "is to provide interested parties with initial guidance regarding implementation of [certain sections] of the [IRA]." *Id.* at 1.

83. The Initial Guidance demonstrates the unbounded authority that the IRA delegates to HHS, and the manner in which HHS will push that authority to its limits absent substantive constraints or external input and review. For example, Section 30 of the Initial Guidance sets forth the agency's final view—adopted without notice and comment—on the selection of negotiation-eligible "qualifying single source drugs" for 2026. *See id.* at 5. Most notably, Section 30 states that

CMS will "identify a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." *Id.* at 8 (footnote omitted).[3] Under Section 30, two distinct drugs that treat two different diseases but share the same active moiety will thus be treated as a qualifying single source drug so long as they have the same NDA holder.

84. This broad interpretation—which strays far from the statutory text—will ensnare large numbers of distinct drug products within the Drug Pricing Program, disrupt manufacturers' phased drug-development processes, and drastically undermine manufacturers' ability to recoup investments on existing drugs. Manufacturers often invest considerable resources to research an existing drug's safety and effectiveness for new patient populations, for example. They also may develop new dosage forms for existing active moieties, such as a tablet or capsule versus an intravenous infusion, or new formulations, such as extended-release or abuse-resistant formulations. These new drug products can provide enormous benefits to patients and caregivers, and under a less expansive interpretation of the statute, at least some of these different products could qualify as distinct qualifying single source drugs. Under the agency's Guidance, however—which the agency specified was "final" in this regard and not subject to notice and comment—all of these different products are lumped together.

85. Combining distinct products can have the effect of eliminating much of the period of market pricing that the IRA purports to preserve. Consider a manufacturer that holds NDAs for Drug A and Drug B, each of which is marketed under separate new drug applications pursuant to

[3] A drug's "active moiety" "is the molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3.

21 U.S.C. § 355(c) and is not the reference listed drug for generic competitors. Drug A has been on the market for fifteen years, while Drug B has been on the market only for two years. Under Section 30, if Drug A and Drug B share an active moiety, they will be treated collectively as one qualifying single source drug. And because Drug A has been on the market for more than seven years, the combined "drug" will be negotiation-eligible, *see* 42 U.S.C. § 1320f–1(e)(1)(A), even though Drug B has been on the market for only two years. The manufacturer thus stands to lose five years of market pricing for—and five years' opportunity to recoup its investment in—Drug B.

86. That interpretation eliminates incentives for manufacturers to continue research and development for existing drugs. Under the broad definition of qualifying single source drug set forth in Section 30, a manufacturer has no reason to invest years and billions of dollars of resources researching whether an active moiety in an existing drug could also be used to treat a different patient population, for example, or could be delivered in a new dosage form or formulation. If the manufacturer continues to innovate in one of these ways, the new drug's eligibility for MFP negotiation will be tied to the eligibility timeline of the existing drug, preventing the manufacturer from earning market returns on the new drug for the full period the statute authorizes.

87. These harms are not limited to the selection of qualifying single source drugs for MFP price setting in 2026. The scope of what constitutes a qualifying single source drug carries through the Drug Pricing Program and determines where an eligible drug is ranked for possible negotiation, *see* 42 U.S.C. § 1320f–1(b)(1)(A), as well as the maximum-fair-price ceiling if the drug is selected, *see id.* § 1320f–3(c).

88. Treating multiple products as one qualifying single source drug also harms providers and patients. As explained, when a provider-administered product is selected for price

controls under the Drug Pricing Program, reimbursements for administering the drug decrease along with the price. Consequently, if more distinct products are lumped together and included in the Program, a broader swath of the treatments providers administer will have their reimbursement rates slashed. Some existing treatments may no longer be offered to patients who need them, and future treatments may never be developed.

89. Other aspects of the Initial Guidance similarly abuse the statutory text. The statute provides that a drug or biological product is not eligible for price setting if it faces competition from a generic drug or biosimilar that has been "marketed." 42 U.S.C. § 1320f–1(e)(1)(A), (B). The Initial Guidance states, however, that "CMS will review [Medicare Part D claims] data … during [a] 12-month period … and will consider a generic drug or biosimilar biological product to be marketed when that data reveal that the manufacturer of that drug or product has engaged in *bona fide marketing* of that drug or product." Initial Guidance, *supra*, at 10 (emphasis added). In other words, to determine whether a drug or product has been "marketed," CMS will review data showing only whether the drug or product has been prescribed to Medicare Part D beneficiaries and whether Part D insurance plans cover it. There is no statutory basis for this "bona fide marketing" standard. Nor is there a statutory basis for CMS's statement that it plans to "monitor the manufacturers of generics or biosimilar biological products to ensure they are engaging in bona fide marketing." *Id.* And again, CMS promulgated this Guidance without allowing for notice and comment from stakeholders.

90. Still other aspects of the Initial Guidance further underscore the broad authority that HHS has assumed under the IRA. For example, the Initial Guidance proposes a gag rule, stating that "CMS intends to require that a [manufacturer of a drug selected for negotiation] shall not disclose to the public any information in the initial offer or any subsequent offer by CMS, the

ceiling price contained in any offer, or any information contained in any concise justification provided with an offer." *Id.* at 30. At the same time, the Guidance incorporates only a cursory, one-line statement indicating that "CMS intends to implement a confidentiality policy" to protect proprietary information that manufacturers submit during the negotiation process. *Id.* at 29. The Initial Guidance thus exacerbates the already one-sided "negotiation" process: HHS may demand whatever proprietary information it wants from manufacturers—on pain of massive daily fines and with no guarantees of confidentiality or information security—while simultaneously demanding that manufacturers "agree" to agency-imposed prices and prohibiting manufacturers from disclosing any information about the process that led to those prices.

91. CMS adopted its interpretation of "qualifying single source drug" and "market[ing]" as final for 2026, without notice or any opportunity for manufacturers, providers, patients, or the public to comment. *See id.* at 2, 7-10. And while CMS voluntarily solicited comments on other aspects of the Drug Price Negotiation Program, it has made no commitment to consider or respond to the comments received in any substantive way. Furthermore, the agency has reserved the right to "make changes to any policies, including policies on which CMS has not expressly solicited comment," at any time. *Id.* at 2. Manufacturers and others submitting comments thus have no assurance that CMS will actually take their comments into account, or that it will not later completely change its implementation approach in the future, again without notice and an opportunity for comment.

92. The Initial Guidance is thus an early and clear example of the extreme manner in which HHS intends to wield the broad authority Congress has delegated under the IRA, and evidence of the significant harms that will flow to pharmaceutical manufacturers and innovation in the United States as a result.

The Penalties Used to Coerce Compliance Are Unconstitutionally Disproportionate Under the Eighth Amendment's Excessive Fines Clause

93. The IRA's statutory scheme is also invalid because it mandates an "excise tax" that constitutes an excessive fine. For failing to participate in the sham negotiation process, or failing to "agree" to the resulting so-called "fair price," the IRA imposes an escalating "excise tax" that *begins* at 186% of a drug's total national sales revenue and, after 271 days, reaches a maximum of 1900%. IRA § 11003(a) (codified at 26 U.S.C. § 5000D(b)(1)-(4)). For most selected drugs, those financial penalties would be so massive that no manufacturer could pay them for even a short period; over the course of a single year, they would amount to billions of dollars. That punishment violates the Constitution because it is grossly out of proportion to the "offenses" that trigger the fine.

94. The Eighth Amendment bars the imposition of excessive fines. This provision "limits the government's power to extract payments, whether in cash or in kind, as punishment for some offense." *United States v. Bajakajian*, 524 U.S. 321, 328 (1998) (quoting *Austin v. United States*, 509 U.S. 602, 609–10 (1993)). The Excessive Fines Clause applies not only to criminal fines but also to civil fines designed at least in part to punish. *See Hudson v. United States*, 522 U.S. 93, 103 (1997); *Austin*, 509 U.S. at 609–10. "The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: the amount of the [fine] must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334.

The Excise Tax Imposed on Noncompliant Manufacturers Is Punitive

95. In assessing whether a provision identified as a tax operates as a penalty, the Supreme Court has adopted a "functional approach," under which mere labels are not dispositive. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 565 (2012) (*NFIB*). In related contexts, courts

consider the size and purpose of a fine in determining whether it is punitive. *See Dep't of Revenue of Montana v. Kurth Ranch*, 511 U.S. 767, 780 (1994) (holding, in the context of deciding whether a tax violated the double jeopardy clause, that the tax was punitive because it was more than eight times the drug's market value and was designed not just to raise revenue but also to facilitate anti-crime initiatives); *Dye v. Frank*, 355 F.3d 1102, 1105 (7th Cir. 2004) (holding, in the context of deciding whether a tax violated the double jeopardy clause, that the tax was punitive because "[a] 'tax' that is five times the value of the item taxed is remarkably high and is more consistent with punishing ownership of the item than with raising revenue"). "It matters not whether the scheme has a remedial purpose, even a predominantly remedial purpose." *Tyler v. Hennepin Cnty.*, 143 S. Ct. 1369, 1381 (2023) (Gorsuch, J., concurring). "Because sanctions frequently serve more than one purpose, … the Excessive Fines Clause applies to *any* statutory scheme that serves *in part* to punish." *Id.* (cleaned up).

96. The IRA's excise tax is unquestionably punitive. It has the intended coercive effect of punishing manufacturers that fail to participate in the law's compelled-negotiation process. Indeed, a title summary of an earlier version of the legislation candidly described it as a "steep, escalating penalty" designed to "give[] the HHS Secretary leverage" over manufacturers. Title Summary at 1–2, H.R. 3 (2019). The massive scale of the tax is clearly punitive in nature. *See NFIB*, 567 U.S. at 565 (noting that the fact that a "tax" imposes an "exceedingly heavy burden" weighs in favor of finding it to be a penalty).

97. The excise tax is so large that incurring it would be financially ruinous for PhRMA's members. Indeed, Congress's own analysis shows that the "excise tax" was never intended to raise revenue or to serve any other nonpunitive purpose, but instead to punish any manufacturer who failed to agree to the government's terms, and thereby to deter any manufacturer

from doing so. The Congressional Budget Office score for the IRA presumes that the excise tax will not generate *any* revenue independent of its effects on Medicare drug pricing through imposition of the government's MFP. *See* Congressional Budget Office, *Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14* at 5 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf. Similarly, the Joint Committee on Taxation concluded that an essentially identical "excise-tax" provision in predecessor legislation would have "*no* revenue effect." Joint Comm. on Tax'n, *supra*, at 8 (emphasis added). These conclusions reflect that no manufacturer would dare to actually trigger the excise tax, which is intended solely as a cudgel to force "agreement" to HHS's price controls. This coercive aim makes the excise tax punitive for purposes of the Excessive Fines Clause. *See Bajakajian*, 524 U.S. at 329 (observing that deterrence has "traditionally been viewed as a goal of punishment"); *Tyler*, 143 S. Ct. at 1382 (Gorsuch, J. concurring) ("[A] statutory scheme may … be punitive where it serves another goal of punishment, such as deterrence." (cleaned up)). At the very least, the IRA's excise tax "cannot fairly be said *solely* to serve a remedial purpose." *Id.* at 1381 (quotation marks omitted). Accordingly, "the Excessive Fines Clause applies." *Id.*

98. To be clear, while the excise tax is imposed upon manufacturers, its harms extend more broadly. Without the excise tax, manufacturers could more effectively resist lowball "offers" or "counteroffers" from HHS that do not align with a product's value, and prices and reimbursement rates would continue to reflect the market. The excise tax is thus an integral part of the statutory scheme for setting government-dictated prices, and it will have the direct effect of reducing reimbursements to providers, limiting patient access, and stifling the development of new products.

The Penalty Is Grossly Disproportionate to the Purported Culpability of the Conduct That It Punishes

99. While strict proportionality between the punishment and the gravity of the offense is not required, the Constitution forbids "gross disproportionality." *Bajakajian*, 524 U.S. at 336. Although this inquiry is not "marked by a simple mathematical formula," the Supreme Court has considered three general criteria: "the degree of the defendant's reprehensibility or culpability; the relationship between the penalty and the harm to the victim caused by the defendant's actions; and the sanctions imposed in other cases for comparable misconduct." *Cooper Indus. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 435 (2001) (cleaned up).[4]

100. Consideration of these factors demonstrates that the IRA's excise-tax penalty is grossly disproportionate to the underlying offense of failing to participate in the law's compelled negotiation process. Indeed, that follows *a fortiori* from precedent.

101. ***First***, the supposed "offense" that is being punished—a manufacturer's mere refusal to express its agreement to a price set by HHS—does not entail "reprehensibility or culpability." *Cooper Indus.*, 532 U.S. at 435. The noncompliant conduct involves no "threat of violence," "trickery," or "deceit"; nor does it involve "indifference to or reckless disregard for the health and safety of others," factors that the Supreme Court has indicated might warrant greater penalties. *BMW of N. Am. v. Gore*, 517 U.S. 559, 576 (1996). Indeed, failing to agree on a price for the lawful sale of beneficial medicines is not normally considered to be misconduct at all; it is not even unlawful. *Cf. Bajakajian*, 524 U.S. at 337 ("It was permissible to transport the currency

[4] Federal courts have applied these factors to many different kinds of penalties. *See, e.g.*, *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 387–90 (4th Cir. 2015) (punitive damages and civil penalties); *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1314–16 (11th Cir. 2021) (treble damages and statutory penalties); *Texas v. Penguin Group (In re Elec. Books Antitrust Litig.)*, Nos. 11 MD 2293 (DLC); 12 Civ. 3394 (DLC), 2014 U.S. Dist. LEXIS 77431, *29–33 (S.D.N.Y. June 5, 2014) (civil penalties).

out of the country so long as [it was] reported"). The conduct is also less culpable than the failure-to-report at issue in *Bajakajian*. *See id.* at 324–25 (Bajakajian falsely told customs inspectors that his "family had no additional currency to declare").

102. ***Second***, there is no reasonable relationship between the enormous size of the excise-tax penalty and the harm caused by a manufacturer's refusal to engage in negotiations or to reach an agreement during the sham "negotiation" process. Even if the government can claim a legitimate interest in ensuring that manufacturers' products are sold for no more than the MFP, the excise tax vastly exceeds any alleged harm. Each day that a manufacturer remains noncompliant, it faces a penalty amounting to many times its *total daily revenues* for *all sales* of the relevant drug—a figure that dwarfs the differential between the MFP and actual sales price. This penalty, which could quickly amount to millions of dollars per day, also has no upper limit; a new penalty is assessed *each day* that the manufacturer remains noncompliant. As a result, the penalty would swiftly become ruinous for any manufacturer subject to it. Moreover, the subject "offense" is "unrelated to any other illegal activities," it "affect[s] only … the Government," and it does not involve "fraud on the United States." *Bajakajian,* 524 U.S. at 338–39. The penalty also "bear[s] no correlation to any damages sustained by society or to the cost of enforcing the law, and any relationship between the Government's actual costs and the amount of the sanction is merely coincidental." *Tyler*, 143 S. Ct. at 1381 (Gorsuch, J., concurring) (quotation marks omitted).

103. ***Third***, PhRMA is not aware of *any other statute* that imposes similarly severe sanctions on comparable "misconduct." There are no other statutes that impose penalties—much less crippling penalties on this scale—for mere failure to agree to a price set by the government.

104. In sum, because the IRA's severe and escalating excise-tax penalty does not redress reprehensible or culpable conduct; because there is no reasonable relationship between the excise-

tax penalty and the harm caused by the offense; and because no comparable sanctions are imposed for similar actions, the penalty is clearly grossly disproportionate in violation of the Excessive Fines Clause.

The MFP Provisions Do Not Provide Even Rudimentary Due Process

105. The Due Process Clause of the Fifth Amendment prohibits the federal government from "depriv[ing]" a person of "life, liberty, or property without due process of law." The government violates procedural due process where (1) it deprives a plaintiff of a constitutionally protected liberty or property interest (2) without following constitutionally sufficient procedures. *See Swarthout v. Cooke*, 562 U.S. 216, 219 (2011).

106. The IRA deprives pharmaceutical manufacturers of constitutionally protected property interests—their investment-backed patent rights and common-law right to sell their products at market prices free from arbitrary and inadequately disclosed governmental constraints. The IRA does the same to providers, who will suffer significant losses from arbitrarily reduced reimbursement rates, to the point of being driven out of business. And the statute creates the conditions to deprive patients of current and future medicines that may in many cases be life-sustaining or life-extending. And the IRA does so without following constitutionally sufficient procedures: The statute affords manufacturers, providers, and patients *no* opportunity to be heard regarding key decisions that HHS needs to make in order to implement the Act during the first three years and simultaneously deprives them of any judicial review of those decisions. The combined result is to deny manufacturers, providers, and patients even the most rudimentary process for some of the most consequential issues affecting their vital interests.

The IRA Deprives Manufacturers, Providers, and Patients of Constitutionally Protected Interests

107. As the Supreme Court has explained, the "'property' interests subject to procedural due process protection are not limited by a few rigid, technical forms," *Perry v. Sindermann*, 408 U.S. 593, 601 (1972), and they "extend well beyond actual ownership of real estate, chattels, or money," *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 571–72 (1972). The government can create a constitutionally protected property interest through conduct that sets expectations and induces reliance, including by making promises—whether express or implied—via contract, statute, or patterns and practices. *See Perry*, 408 U.S. at 601 (such a promise need not be explicit, but instead may be "implied from 'the promisor's words and conduct in the light of the surrounding circumstances'" and the "'usage of the past'") (quoting 3 A. Corbin on Contracts §§ 561–572A (1960)). While the government "may elect not to confer a property interest" in the first place, "it may not constitutionally authorize the deprivation of such an interest, once conferred, without appropriate procedural safeguards." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985) (citation omitted).

108. The IRA impairs manufacturers' constitutionally protected property interests in their patent rights. More than a century ago, the Supreme Court announced it "indisputably established" that "rights secured under the grant of letters patent by the United States [are] property." *William Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co.*, 246 U.S. 28, 39–40 (1918). The Court has reaffirmed that proposition numerous times since. *See, e.g.*, *Horne v. Dep't of Agriculture*, 576 U.S.350, 359 (2015) (patent "confers upon the patentee an exclusive property in the patented invention" (quotation marks omitted)); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) ("That a patent is property . . . has long been settled."). Most recently, the Court has noted that treating patents as "public rights" for some purposes does

not mean that "patents are not property for purposes of the Due Process Clause or the Takings Clause." *Oil States Energy Servs., LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1379 (2018).

109. In granting property rights, "[t]he federal patent system … embodies a carefully crafted bargain"—in return for "the creation and disclosure of new, useful, and nonobvious advances in technology and design," the inventor receives "the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). "Patentees value the right to exclude in part because the ability to foreclose competitors from making, using, and selling the invention may allow them an opportunity to obtain above-market profits during the patent's term." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007). "Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace." *King Instruments v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). Accordingly, a scheme that "penalize[es] high prices" for drugs and "thus limit[s] the full exercise of the exclusionary power that derives from a patent" effectively "re-balance[s] the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Biotechnology Indus. Org*, 496 F.3d at 1374.

110. That is precisely what the IRA's Drug Pricing Program purports to allow HHS to do. As noted, pharmaceutical manufacturers invest billions of dollars each year to develop and patent cutting-edge medications. The vast majority of that investment comes up front, well before it can be recouped through sales made during the period of patent exclusivity. Manufacturers accordingly rely on the promise of future sales—and the ability to set the price for their products in accordance with market forces—when structuring their affairs. But the IRA undermines manufacturers' patent rights by severely limiting their ability to recoup investments that they made

years ago—whether by developing their products and patenting them, or by paying to license patents developed by other manufacturers. In so doing, the law disrupts manufacturers' reasonable investment-backed expectations. That is true both with respect to products patented *before* the IRA's passage—where patent rights had fully vested, *see* 35 U.S.C. § 261 ("patents shall have the attributes of personal property")—and also with respect to products in development but not yet patented at the time of enactment.

111. The IRA also disrupts manufacturers' common-law right to sell their products at market prices free from arbitrary governmental constraints. Under the common law, "one of the most treasured" aspects of the right to property is the ability to exclude others from its use except under terms set through voluntary agreements. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021) (quotation marks omitted). For nearly sixty years, the Medicare statute has preserved that common-law right: it has permitted pharmaceutical manufacturers to set drug prices in accordance with market forces. The Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286, for example, did not contain any price-setting restrictions. And when Congress passed legislation creating Part D—"a voluntary program for prescription drug coverage under the Medicare Program," Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066—it included a provision specifically prohibiting HHS from "interfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the price of Part D drugs. 42 U.S.C. § 1395w–111(i)(1). This "noninterference provision" provided manufacturers with a statutory right to continue setting the price for their products according to market forces.

112. In addition to the noninterference provision, the surrounding practices of the Medicare statute have long since created a settled expectation by manufacturers regarding their

ability to determine the prices at which they will offer their products. *See Perry*, 408 U.S. at 601. Over decades of practice, manufacturers have developed more than "a mere subjective 'expectancy' " of their continued ability to sell their products at market prices; they have developed a "legitimate claim of entitlement" through years of "rules and understandings, promulgated and fostered by" the government. *Id.* at 602–03.

113. These interests cannot be dismissed on the grounds that "participation in the Medicare program is voluntary, [and] providers have no constitutionally protected right to be reimbursed in any manner other than that provided by the statute." *Texas Clinical Labs, Inc. v. Shalala*, 1999 WL 1243200, at *4 (N.D. Tex. Dec. 21, 1999). For one thing, pharmaceutical manufacturers spent billions of dollars developing their products long *before* the IRA was enacted. Thus, it cannot be said that manufacturers were "on notice" of such a fundamental change to the legal landscape, nor that they "assumed[] the risk" that their statutory and common-law rights would be revoked. *Id.* at *5. Moreover, manufacturers are not asking to be "reimbursed" by the government *at all*, much less to be reimbursed in any "particular" manner. *Id.* at *4. Rather, manufacturers assert only their historically grounded right to sell their products to willing private buyers at market prices.

114. Manufacturers are also unable to avoid the harms associated with the IRA's deprivation of their property interest by "refus[ing]" to participate in Medicare. *Painter v. Shalala*, 97 F.3d 1351, 1357–58 (10th Cir. 1996). As explained in paragraph 64 above, the IRA delays a manufacturer's ability to exit from Part D of Medicare—and thus compels them to participate in it—for between 11 and 23 months. *See* 42 U.S.C. § 1395w–114c(b)(4)(B)(ii). If a manufacturer's Part D drugs were selected for forced "negotiation" during this period, the manufacturer would be

subject to the punitive excise tax. *See* 26 U.S.C. § 5000D(c)(1). By the time the manufacturer was finally permitted to exit the program, it may have suffered severe financial harm.[5]

115. Nor can manufacturers simply withdraw from Part B of Medicare. For a drug to be covered under Part B, "the manufacturer must have entered into and have in effect a [Medicaid] rebate agreement." 42 U.S.C. § 1396r-8(a)(1). While a manufacturer could theoretically choose not to enter into a rebate agreement, such a choice would mean that *all* of its products could lose coverage under Part B (as well as Medicaid). That is a severe and "coerc[ive]" consequence in itself. *NFIB*, 567 U.S. at 585.

116. Even if manufacturers' involvement in Medicare were not legally mandated, moreover, their participation is not truly voluntary as a *practical* matter. Medicare accounts for a commanding percentage of the overall market for pharmaceuticals. "The federal government dominates the healthcare market. Through Medicare and Medicaid, it pays for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 699 (3d Cir. 2023) (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022)). And Medicare accounts for the lion's share of the market for many individual drugs. Accordingly, manufacturers have no realistic option of not participating. *Cf. Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019) ("Medicare stands as the largest federal program after Social Security" and "touches the lives of nearly all Americans"). Thus, manufacturers face extraordinary economic pressure to participate—to say nothing of political pressures and the imperative to provide critical medicines to American seniors. *See Tenoco Oil Co. v. Dep't of Consumer Affs.*, 876 F.2d 1013, 1027 n.21 (1st Cir. 1989) ("This

[5] Manufacturers agree to provide steep discounts under other government drug programs, such as Medicaid and Section 340B of the Public Health Service Act. But unlike the IRA, those programs set prices in a direct and transparent manner, *see* 42 U.S.C. § 1396r–8; *id.* § 256b, allowing manufacturers to make an informed decision in advance about whether to participate.

supposed freedom to temporarily leave the market may be largely illusory, however. Even if the wholesalers hoarded their present inventories to be sold when they could obtain a higher price, they still would have to meet their fixed costs—overhead, salaries, storage, etc. In practice, such a course might very well be economically prohibitive."); *cf. Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (recognizing that "total withdrawal of federal funding" can be "economic dragooning" and "a gun to the head").

117. The IRA also deprives providers of their protected property interests. To begin with, providers have a protected interest in being reimbursed for the treatments they provide on a non-arbitrary basis as provided by the Medicare statute. Providers also have a protected interest in continuing to operate their businesses. For years, many providers and entities that administer biologics have invested time and money to create operational methods that minimize patient costs (in terms of time and money) while allowing the entity to remain financially viable. The IRA deprives these providers of their ability to continue their successful and investment-backed operations without unnecessary and arbitrary interference from the government that will ultimately force providers to shut their doors.

118. Finally, patients have an interest in being able to access life-sustaining and life-extending medicines, an interest of which the IRA deprives them without any constitutionally required process. For medicines already on the market, HHS may set an unreasonably low price—or threaten to set an unreasonably low price—that could force a manufacturer to withdraw its products from Medicare and Medicaid or otherwise could delay access to innovative medicines. For medicines in development, manufacturers may cease research when faced with future pricing that will not be sufficient to recoup their investment, depriving patients of the ability to purchase treatments and cures without any opportunity to be heard before the government takes this action.

The Procedures Afforded by the IRA Are Not Constitutionally Sufficient

119. To determine whether the government has afforded constitutionally adequate procedures when depriving a person of a protected interest, courts balance "(1) the private interest at stake; (2) the risk of an erroneous deprivation of that interest through the procedures used and the probable value (if any) of alternative processes; [and] (3) the government's interest, including the possible burdens of alternative procedures." *O'Connor v. Pierson*, 426 F.3d 187, 197 (2d Cir. 2005) (citing *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976)).

120. Where, as here, the government has provided *no process* whatsoever, it is so self-evidently inadequate as a constitutional matter that it is doubtful that undertaking the *Mathews* test is even necessary. *See Schepers v. Comm'r*, 691 F.3d 909, 915 (7th Cir. 2012) (noting "glaring problem" with applying *Mathews* to a government "policy [that] provides *no process* whatsoever to an entire class of registrants"). But if it is necessary to apply the test here, the IRA flunks it.

121. ***First***, the private interests at stake are indisputably massive. As noted, being subject to an MFP has profound economic effects for each and every manufacturer. Indeed, in some instances, the economic viability of a multi-billion-dollar product may turn *entirely* on HHS's decision whether the product is subject to a MFP negotiation. The private interests at stake for providers are similar. Providers, including members of NICA, have invested enormous resources into building facilities and processes for obtaining and administering drugs reimbursed by Medicare effectively and efficiently. For many providers, whether and to what extent MFP price controls slash reimbursement rates for a given drug may make the difference between profit and loss and between continuing to operate and going out of business. For patients, such as those served by NICA members and those represented by GCCA, the decision may be one of life and death, as the consequences of HHS's decisions could determine whether existing products remain available

to Medicare (and Medicaid) beneficiaries and whether future products are brought to market for *any* patients.

122. ***Second***, the risk of erroneous deprivation is high. The IRA leaves many key implementation questions unanswered, apparently leaving HHS to fill in statutory gaps as it sees fit. For example, the Act does not identify the bases on which it is permissible for HHS to reject a drug manufacturer's counteroffer during the negotiation process, except to say that HHS may not accept a counteroffer that exceeds a specified price ceiling or temporary price floor for a limited subset of products. *See* 42 U.S.C. § 1320f–3(b)(2)(F).

123. And yet, for many of these open questions, the IRA provides interested parties *no opportunity* for input into HHS's decision-making, let alone an opportunity to challenge the decisions.

124. Under the IRA, HHS's implementation of the Drug Pricing Program will *not* go through the standard notice-and-comment process that ordinarily applies to agency rulemaking in general and to rulemaking under Medicare in particular. *See* 5 U.S.C. § 553; 42 U.S.C. § 1395hh. Notice-and-comment rulemaking is a basic feature of administrative governance that protects against arbitrary and unlawful agency action. But HHS is required to implement the Drug Pricing Program "by program instruction or other forms of program guidance"—that is, through *sub*-regulatory guidance—for the first three years of price controls, when HHS is charting the path that the Program may follow for years to come. IRA § 11001(c). The law thus provides no mechanism for affected persons or entities—including pharmaceutical manufacturers that will be subject to MFP caps, or the patients or providers who will be affected by them—to observe, comment on, or contribute to the decision-making process.

125. The statute also purports to bar review of a number of HHS's implementation determinations. The Act provides that "[t]here shall be no administrative or judicial review" of, among other things, "[t]he selection of drugs," "the determination of negotiation-eligible drugs," or "[t]he determination of a maximum fair price under [the Act]." 42 U.S.C. § 1320f–7(2)–(3).

126. In combination, these features create the apparently unprecedented situation that the public and regulated entities will have *no* opportunity to weigh in on key determinations by HHS—neither on the front end (*i.e.*, before they are made), nor on the back end (*i.e.*, after they become final). And the barriers to withdrawing from the program, including the 11-to-23-month lock-in period, compound this problem substantially: Manufacturers and providers will be stuck with the agency's implementation choices, even if those choices mean the manufacturer would be better off opting out, and even if it would force providers to shut down completely—and in the process, denying patients access to much-needed medicines.

127. ***Third***, the government has no legitimate interest in completely insulating HHS's decision-making from input from regulated parties or the public, or in denying judicial review even for basic statutory questions. "[T]he due process clause requires, at minimum, that the government provide notice and some kind of hearing before final deprivation of a property interest." *Propert v. District of Columbia*, 948 F.2d 1327, 1331 (D.C. Cir. 1991). Yet the IRA affords no such hearing for many of HHS's most consequential decisions implementing the law. This lack of procedure cannot be justified by any valid governmental interest. Affording interested parties the opportunity to comment on and contribute to decisions about the law's implementation, and to seek review of statutorily impermissible or irrational choices, would impose only minimal "fiscal and administrative burdens." *Mathews*, 424 U.S. at 335. And such external input would also go a long way to reducing "the risk of an erroneous deprivation" of public and private interests. *Id.*

128. Indeed, CMS's promulgation of the Initial Guidance lacked even rudimentary due process. CMS claimed that the IRA exempted the Initial Guidance from APA notice-and-comment procedures. *See* Initial Guidance, *supra*, at 2. CMS thus provided manufacturers and providers with *no* opportunity for input into fundamental decisions, including the definitional guidelines that will determine what drugs will be eligible for MFP negotiation. For instance, CMS adopted an extremely broad definition of qualifying single source drug and an extremely narrow definition of generic or biosimilar "market[ing]." CMS also refused to even commit to publicly releasing the final text of the "agreement" manufacturers will be forced to sign before the selected drug list for 2026 is published—much less to allow manufacturers to review and comment on it. *See* Initial Guidance, *supra*, at 27 (stating only that "CMS will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list for initial price applicability year 2026 is published"). And CMS did so through a decision-making process that manufacturers, providers and patients could not observe, comment on, or contribute to and for which the IRA purports to bar *any* administrative or judicial review. *See* 42 U.S.C. § 1320f–7(2)–(3).

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Nondelegation – Separation of Powers)

129. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

130. The Constitution provides that "All legislative Powers . . . shall be vested in a Congress of the United States." U.S. Const., Art. I, § 1. Accordingly, Congress cannot delegate to other branches of government the authority to make basic policy decisions that the Constitution vests exclusively in the Legislature.

131. Consistent with that principle, when Congress has in the past sought to displace market mechanisms and authorize a government agency to set pricing, it has traditionally taken care to guard against arbitrary agency action: specifying the substantive legal standard by which the agency will set rates and prices; building in procedural protections to ensure that prices are reasonable and protect the interests of sellers, while simultaneously safeguarding the public's interest in avoiding market distortions and shortages; and imposing judicial review as an independent check against improper or erroneous administrative decision-making.

132. The IRA provides no such protections. Congress granted HHS virtually unfettered discretion to set drug prices, and provided no substantive guidance or intelligible principle other than to specify the minimum discount the agency could accept. Congress also provided no opportunity for input by manufacturers, providers, patients, or the public, nor any mechanism for external review of the agency's decisions—and indeed, barred judicial review of many decisions critical to pricing determinations under the Act.

133. The IRA executes this impermissible arrogation of unfettered legislative power to CMS by denying manufacturers any practical way to escape the price setting regime. The statute leaves manufacturers subject to the IRA with three untenable options: (a) agree to whatever price the government demands, even if the price does not remotely approximate the drug's market price; (b) pay a massive excise tax that escalates to 1900% of the drug's total revenues; or (c) give notice for all of the manufacturer's drugs to exit the Medicare and Medicaid programs, but wait 11-23 months before that termination takes effect. Through the creation of this Hobson's choice for drug manufacturers, Congress transferred legislative power to CMS in violation of Article 1, Section 1 of the U.S. Constitution.

134. The IRA Drug Pricing Program is therefore unconstitutional under nondelegation and separation-of-powers principles and must be enjoined.

SECOND CLAIM FOR RELIEF

(Eighth Amendment – Excessive Fines Clause)

135. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

136. The Eighth Amendment bars the imposition of excessive criminal fines and excessive civil fines designed at least in part to punish.

137. A fine is unconstitutional under the Eighth Amendment where the amount of the fine is grossly disproportionate to the gravity of the offense that the fine is designed to punish.

138. Although labeled a "tax," the IRA's excise tax functions as a penalty. The excise tax punishes manufacturers that fail to participate in the IRA's compelled-negotiation process in order to force manufacturer compliance with the IRA. And in so doing, the excise tax harms providers as well.

139. The excise-tax penalty is grossly disproportionate to the culpability of the conduct that it punishes. The size of the excise-tax penalty is staggering, reaching as high as 1900% of the total daily revenues for all sales of the relevant drug and compounding for each day of "noncompliance." At the same time, the supposed "offense" that the excise-tax penalty is designed to punish—a manufacturer's mere refusal to "agree" upon a price—is not normally considered to be misconduct at all, let alone egregiously unlawful conduct.

140. No other statute imposes similarly severe sanctions on comparable "misconduct."

141. The IRA excise tax is therefore unconstitutional under the Eighth Amendment Excessive Fines Clause and must be enjoined.

THIRD CLAIM FOR RELIEF

(Fifth Amendment – Due Process)

142. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

143. The Fifth Amendment Due Process Clause prohibits the government from depriving a person or entity of a constitutionally protected property interest without following constitutionally sufficient procedures.

144. The IRA Drug Pricing Program deprives pharmaceutical manufacturers of two constitutionally protected property interests: their investment-backed patent rights and common-law right to sell their products at market prices free from arbitrary and inadequately disclosed governmental constraints. It also deprives providers of their interest in adequate reimbursement—in some cases threatening their ability to continue serving Medicare patients or even to stay in business—and it deprives patients of their access to life-sustaining and life-extending medicines.

145. This deprivation is not voluntary.

146. The IRA Drug Pricing Program forces this deprivation without following constitutionally sufficient procedures. The Act denies pharmaceutical manufacturers, providers, and patients even the most rudimentary process, by failing to provide manufacturers, providers, and patients with any opportunity to weigh in on key determinations by HHS on the "front" end (*i.e.*, before decisions are made) and by foreclosing judicial and administrative review of those determinations on the "back" end (*i.e.*, after decisions have been made).

147. The risk of erroneous deprivation resulting from this lack of process is high, and the government has no legitimate interest in insulating HHS's decisions from manufacturer, provider, or patient input or judicial review.

148. The IRA Drug Pricing Program is therefore unconstitutional under the Fifth Amendment Due Process Clause and must be enjoined.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiffs request a judgment in their favor against Defendants as follows:

1. Declare that the IRA Drug Pricing Program violates nondelegation and separation-of-powers principles and is unconstitutional;
2. Declare that the IRA excise tax violates the Eight Amendment Excessive Fines Clause and is unconstitutional;
3. Declare that the IRA Drug Pricing Program violates Plaintiffs' members' Fifth Amendment due process rights, and those of patients represented by GCCA, and is unconstitutional;
4. Enjoin HHS from implementing the IRA Drug Pricing Program because it violates separation-of-powers principles and is unconstitutional;
5. Enjoin HHS from enforcing the IRA excise tax;
6. Enjoin HHS from implementing the IRA Drug Pricing Program in a manner that does not incorporate adequate procedural processes, including the opportunity for public notice and comment regarding key implementation decisions and for judicial review regarding issues of statutory interpretation;
7. Award Plaintiffs their reasonable attorneys' fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and
8. Grant such other and further relief as the Court may deem appropriate.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 4.

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